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August 11, 2005

### VIA UPS NEXT DAY AIR

Dr. Robert Moore
Office of Nutritional Products,
Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Pkwy.
College Park, MD 20740

Re: Fulfillment of Reporting Obligation Under 21 U.S.C. 343(r) and 21 C.F.R. 101.93

Dear Dr. Moore:

We hereby submit on behalf of Caudill Seed Company,<sup>1</sup> in accordance with 21 U.S.C. 343(r) and 21 CFR 101.93, an original and two copies of its notification. Caudill Seed Company retains scientific documentation supporting the statements. Please find enclosed a certification from Caudill Seed Company that the information contained in this notice is complete and accurate and that Caudill Seed Company has substantiation that the statements are truthful and not misleading.

#### Supplement Brand Name

Vitalica

### **Supplement Ingredients**

Sulforaphane glucosinolate Cruciferous seed extract Hypromellose Sodium Starch Glycolate Microcrystalline Cellulose Magnesium Stearate Chlorophyllin

97S 0162 LET 16 716

## **Text of Statements of Nutritional Support**

<sup>&</sup>lt;sup>1</sup> The address for Caudill Seed Company is 1402 West Main Street, Louisville, KY 40203

- Sgs glucosinolate activates the body's natural detoxification and antioxidant enzymes, protecting cells from free radical damage.
- Scientists at Johns Hopkins School of Medicine identified sgs as a natural long-lasting antioxidant and detoxifier found in broccoli and broccoli sprouts.
- Sgs contributes to the integrity of cells, promoting the body's immune defense systems for overall health and well-being.
- Vitalica, the sgs dietary supplement, activates the body's natural detoxification and antioxidant enzymes, protecting cells from free radical damage.
- Each Vitalica capsule delivers 30 mg sgs, the indirect antioxidant and detoxifier.
- Johns Hopkins researchers believe that sgs contributes to the integrity of cells, promoting the body's immune defense systems for overall health and well-being.
- Scientific research indicates that sgs supports antioxidant activity in the body.
- It is a long-lasting antioxidant that triggers Phase 2 enzymes that help to remove free radicals and other chemicals that may cause DNA damage.
- Sgs is an indirect antioxidant—it does not neutralize free radicals directly, but rather boosts Phase 2 enzymes that trigger ongoing and long-lasting antioxidant activity.
- The sgs indirect antioxidant may continue to protect cellular health for up to 96 hours.
- The Johns Hopkins discovery that promotes detoxification, antioxidation, and cellular integrity.
- One consequential component of this diet can be broccoli, validated when Johns Hopkins University School of Medicine identified its high concentration of sgs glucosinolate, a natural occurring antioxidant.
- In its precursor form, sulforaphane glucosinolate or sgs functions as an indirect antioxidant.
- Indirect antioxidants have long-lasting effects, triggering broad-spectrum free radical elimination that may last for days.
- The same scientists at Johns Hopkins University School of Medicine, who made the discovery, believe that sgs contributes to the integrity of cells, boosting the body's immune defense systems for overall health and well-being.

• Upon this foundation arises the introduction of Vitalica, the daily sgs dietary supplement that promotes detoxification, antioxidation, and cellular integrity.

In accordance with 21 USC 343(r)(6) and 21 CFR 101.93(c), each of the above statements will be followed by an asterisk that will be cross-referenced to another asterisk on the very same panel or page next to which the following statement will appear in a box and in bold face type: "These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

Respectfully submitted,

Jonathan W. Emord Claudia A. Lewis-Eng

Encl.

# Certification

information contained in the foregoing notice is complete and accurate and that Caudill See
into the domained in the totagonia house is complete and document and that Caudin 500
Company, Inc., has substantiation that the statements are truthful and not misleading.
Executed on: 6-905